



PHILIP MORRIS
PRODUCTS S.A.

June 8, 2017

Ms. Ann Simoneau
Director, Office of Compliance and Enforcement
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted via ESG

**Re: Response to Office of Compliance and Enforcement Request for
MR0000059 IQOS system with Marlboro HeatSticks;
MR0000060 IQOS system with Marlboro Smooth Menthol HeatSticks; and
MR0000061 IQOS system with Marlboro Fresh Menthol HeatSticks**

Dear Ms. Simoneau,

Further to your Inspection Request letter dated May 25, 2017, please find herewith the requested information in [Appendix A](#) for the mentioned facilities.

We confirm that the inspection team will be able to observe the manufacturing and testing processes of the MRTPA products during the periods mentioned and that records related to the manufacturing, quality control, ex-batch release and stability testing are accessible and can be reviewed during the scheduled inspections.

This response contains confidential commercial and/or trade secret information. Protection of this information from public disclosure is hereby claimed under the applicable provisions of United States law. We request the agency to provide pre-disclosure notification and follow the procedures in 21 C.F.R. §20.61(e) before publicly disclosing any information contained in the response.

We remain available for any further information that is required.

Sincerely,

Malgorzata Wronowska, PhD
Director Regulatory and Scientific Affairs
Philip Morris Products S.A.

Jeffrey Walker, M.D.
US Agent for PMP S.A.
CEO, Teton Regulatory Sciences

cc: Matthew R. Holman, Ph.D.
Director, Office of Science
Center for Tobacco Products



Appendix A:

Firm Name:	Philip Morris Products S.A. (PMP S.A.)																					
Location:	Quai Jeanrenaud 3 Neuchatel 2000 Switzerland																					
Operator:	Philip Morris Products S.A.																					
Contact Name: Phone No.: Fax No.: Email:	Shelley Moores Work: +41 (58) 242 2033 Mobile: +41 (79) 673 3398 +41 (58) 242 2811 Shelley.Moores@pmi.com																					
Production schedule for manufacturing activities for MRTPA products	<p>Production of MRTPA Tobacco Powder (blending and grinding) is scheduled during weeks 33, 37 and 46 in 2017; weeks 03 and 11 in 2018.</p> <p>Non-MRTPA Tobacco Powder is produced on a regular basis.</p> <p>No production will occur during the following local holidays:</p> <table border="1"><thead><tr><th>Holidays</th><th>Week #</th><th>Dates</th></tr></thead><tbody><tr><td>National Holiday</td><td>31</td><td>1 Aug 2017</td></tr><tr><td>Federal Fast Day</td><td>38</td><td>18 Sept 2017</td></tr><tr><td>Christmas Day</td><td>52</td><td>25 Dec 2017</td></tr><tr><td>New Year's Day</td><td>01</td><td>1 Jan 2018</td></tr><tr><td>Independence Day</td><td>09</td><td>1 Mar 2018</td></tr><tr><td>Good Friday</td><td>13</td><td>30 Mar 2018</td></tr></tbody></table>	Holidays	Week #	Dates	National Holiday	31	1 Aug 2017	Federal Fast Day	38	18 Sept 2017	Christmas Day	52	25 Dec 2017	New Year's Day	01	1 Jan 2018	Independence Day	09	1 Mar 2018	Good Friday	13	30 Mar 2018
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Appendix A (cont'd):

Firm Name:	Philip Morris Manufacturing and Technology Bologna S.p.A. (PMMTB)																																	
Location:	Via Fratelli Rosselli 4 40069 Zola Predosa Bologna Italy																																	
Operator:	Philip Morris Manufacturing and Technology Bologna S.p.A.																																	
Contact Name: Phone No.: Fax No.: Email:	Shelley Moores Work: +41 (58) 242 2033 Mobile: +41 (79) 673 3398 +41 (58) 242 2811 Shelley.Moores@pmi.com																																	
Production schedule for manufacturing activities for MRTPA products	<p>Production of Tobacco Sticks for MRTPA product will take place in September 2017, October 2017, December 2017, February 2018 and April 2018.</p> <p>The detailed weekly production schedule is defined 2 months before production and can be changed based on needs.</p> <p>Non-MRTPA Tobacco Sticks are produced on a regular basis.</p> <p>No production will occur during the following local holidays:</p> <table border="1"><thead><tr><th>Holidays</th><th>Week #</th><th>Dates</th></tr></thead><tbody><tr><td>National Holiday</td><td>33</td><td>15 Aug 2017</td></tr><tr><td>All Saints Day</td><td>44</td><td>1 Nov 2017</td></tr><tr><td>Immaculate Conception Day</td><td>49</td><td>8 Dec 2017</td></tr><tr><td>Christmas Day</td><td>52</td><td>25 Dec 2017</td></tr><tr><td>St Stephens Day</td><td>52</td><td>26 Dec 2017</td></tr><tr><td>New Year's Day</td><td>01</td><td>1 Jan 2018</td></tr><tr><td>Epiphany</td><td>01</td><td>6 Jan 2018</td></tr><tr><td>Easter Day</td><td>13</td><td>1 Apr 2018</td></tr><tr><td>Easter Monday</td><td>14</td><td>2 Apr 2018</td></tr><tr><td>Liberation Day</td><td>17</td><td>25 Apr 2018</td></tr></tbody></table>	Holidays	Week #	Dates	National Holiday	33	15 Aug 2017	All Saints Day	44	1 Nov 2017	Immaculate Conception Day	49	8 Dec 2017	Christmas Day	52	25 Dec 2017	St Stephens Day	52	26 Dec 2017	New Year's Day	01	1 Jan 2018	Epiphany	01	6 Jan 2018	Easter Day	13	1 Apr 2018	Easter Monday	14	2 Apr 2018	Liberation Day	17	25 Apr 2018
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Appendix A (cont'd):

Firm Name:	(b) (4)
Location:	(b) (4)
Owner:	(b) (4)
Contact Name: Phone No.: Fax No.: Email:	(b) (4)
Production schedule for manufacturing activities for MRTPA products	No production takes place at this facility. Activity: Sensory evaluation for stability studies Sensory evaluation will be performed on Fresh Menthol Tobacco sticks as part of a stability study during weeks 35 and 36, 2017.



Appendix A (cont'd):

Firm Name:	Philip Morris International Research Laboratories Pte Ltd (PMIRL)																											
Location:	50 Science Park Road #02-07 The Kendall Singapore Science Park II Singapore 117406																											
Operator:	Philip Morris International Research Laboratories Pte Ltd																											
Contact Name: Phone No.: Fax No.: Email:	Shelley Moores Work: +41 (58) 242 2033 Mobile: +41 (79) 673 3398 +41 (58) 242 2811 Shelley.Moores@pmi.com																											
Production schedule for manufacturing activities for MRTPA products	<p>This site performs compliance sampling-checks of device Certificate of Conformity records.</p> <p>No activity will occur during the following local holidays:</p> <table border="1"><thead><tr><th>Holidays</th><th>Week #</th><th>Dates</th></tr></thead><tbody><tr><td>Hari Raya Puasa</td><td>26</td><td>26 Jun 2017</td></tr><tr><td>National Day</td><td>32</td><td>9 Aug 2017</td></tr><tr><td>Hari Raya Haji</td><td>35</td><td>1 Sep 2017</td></tr><tr><td>Deepavali</td><td>42</td><td>18 Oct 2017</td></tr><tr><td>Christmas Day</td><td>52</td><td>25 Dec 2017</td></tr><tr><td>New Year's Day</td><td>01</td><td>1 Jan 2018</td></tr><tr><td>Chinese New Year</td><td>07</td><td>16-17 Feb 2018</td></tr><tr><td>Good Friday</td><td>13</td><td>30 Mar 2018</td></tr></tbody></table>	Holidays	Week #	Dates	Hari Raya Puasa	26	26 Jun 2017	National Day	32	9 Aug 2017	Hari Raya Haji	35	1 Sep 2017	Deepavali	42	18 Oct 2017	Christmas Day	52	25 Dec 2017	New Year's Day	01	1 Jan 2018	Chinese New Year	07	16-17 Feb 2018	Good Friday	13	30 Mar 2018
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Contact Name: Phone No.: Fax No.: Email:	(b) (4)																																	
Production schedule for manufacturing activities for MRTPA products	<p>The Tobacco Heating Device (THD) will be produced in October 2017, December 2017, February 2018 and April 2018.</p> <p>The detailed weekly production schedule is defined 2 months before production and can be modified to meet business needs.</p> <p>No production is scheduled during the following local holidays:</p> <table border="1"><thead><tr><th>Holidays</th><th>Week #</th><th>Dates</th></tr></thead><tbody><tr><td>Hari Raya Puasa</td><td>26</td><td>26 Jun 2017</td></tr><tr><td>National Day</td><td>35</td><td>31 Aug 2017</td></tr><tr><td>Hari Raya Haji</td><td>35</td><td>1 Sep 2017</td></tr><tr><td>Hari Malaysia</td><td>37</td><td>16 Sep 2017</td></tr><tr><td>Deepavali</td><td>42</td><td>18 Oct 2017</td></tr><tr><td>Maulidur Rasul</td><td>48</td><td>1 Dec 2017</td></tr><tr><td>Christmas Day</td><td>52</td><td>25 Dec 2017</td></tr><tr><td>New Year's Day</td><td>01</td><td>1 Jan 2018</td></tr><tr><td>Chinese New Year</td><td>07</td><td>16-17 Feb 2018</td></tr><tr><td>Sultan's Birthday</td><td>12</td><td>23 Mar 2018</td></tr></tbody></table>	Holidays	Week #	Dates	Hari Raya Puasa	26	26 Jun 2017	National Day	35	31 Aug 2017	Hari Raya Haji	35	1 Sep 2017	Hari Malaysia	37	16 Sep 2017	Deepavali	42	18 Oct 2017	Maulidur Rasul	48	1 Dec 2017	Christmas Day	52	25 Dec 2017	New Year's Day	01	1 Jan 2018	Chinese New Year	07	16-17 Feb 2018	Sultan's Birthday	12	23 Mar 2018
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